EXHIBIT Q

May 15, 2020

Via Email

Orrick, Herrington & Sutcliffe LLP
701 Fifth Avenue
Suite 5600
Seattle, WA 98104-7097

+1 206 839 4300
orrick.com

Jeffrey B. Coopersmith

E jcoopersmith@orrick.com
D 206 839 4339
F +1 206 839 4301

Jeff Schenk
Assistant United States Attorney
U.S. Attorney's Office
Northern District of California
150 Almaden Blvd. Suite 900
San Jose, CA 95113
Jeffrey.B.Schenk@usdoj.gov

Re: United States v. Balwani, Case No. 18-cr-00258-EJD
Outstanding Production of FDA and CMS Documents

Dear Jeff:

I am writing to follow up on my letter to Bob Leach dated March 30, 2020, to which we have not received a response. As noted in my March 30 letter, we have grave concerns with the integrity of the FDA's document production, and the government's approach to the production of FDA and CMS documents. Although the government has attempted to minimize the importance of these productions to the Court, the FDA is a focal point in the government's March 23, 2020 Bill of Particulars and is referenced 17 times in that document.

We received the government's recent productions of new FDA documents, including the most recent productions in the past three weeks. Incredibly, despite the various representations the government made to the Court in 2019 about the completeness of the productions and the pendency of the defense requests for over a year, and after a Court order, the government's recent productions not only include new documents from Tier 1 custodians, but also crucial *Brady* evidence from these custodians that contradicts the government's case as well as sworn testimony from FDA witnesses at civil depositions. These documents should and would have surfaced over a year ago had the government simply performed a search for "Theranos" from Tier-1 custodians. The government's failure to perform even this basic procedure does not inspire confidence.

Although we are glad to finally have additional critical documents that should have been produced long ago (and indeed should have been considered by the government and grand jury before proceeding), the very late production of key evidence from core custodians only increases our concerns about the integrity of the productions and suspicions that all documents required by the Court's order, including all *Brady* materials, have yet to be produced.

We do not know all the circumstances that have led us to this point, where almost two years after indictment key exculpatory document is being dribbled out raising serious questions about what

is still be withheld. And as noted in my March 30 letter, the FDA's admission that it intentionally withheld material is particularly troubling. At the very least, there appears to be a root cause problem tied to the government's "hands off" approach to its discovery obligations, including tolerance for manual, self-collections by FDA custodians whose conduct is suspect.

At a minimum, and as requested in my March 30 letter, the government must provide a full accounting of its collection and production methodology with respect to both FDA and CMS as part of the need to do everything possible to ensure that the agencies are not continuing to withhold critical documents. As Department of Justice attorneys operating under a Court order, you can have no greater confidence in the agencies' efforts than we do based on the above and other recent findings by the defense, and you should have the same interest in transparency as we do.

Finally, please let us know if the government plans to produce additional FDA and CMS documents, and when the government plans to give us a full accounting and certify full compliance with the Court's order.

We look forward to the government's response to my March 30, 2020 letter as well as this one.

Very truly yours,

Jeffrey B. Coopersmith

cc: Lance Wade (LWade@wc.com)
Robert S. Leach (Robert.Leach@usdoj.gov)

4157-0869-9684.1

U.S. Department of Justice

United States Attorney
Northern District of California

150 Almaden Boulevard, Suite 900
San Jose, California 95113

(408) 535-5061
Fax:(408) 535-5066

March 6, 2020

VIA EMAIL

Lance Wade
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, DC 20005

Jeffrey B. Coopersmith
Orrick Herrington & Sutcliffe LLP
701 5th Avenue, Suite 5600
Seattle, WA 98104-7097

Re: United States v. Elizabeth Holmes and Ramesh "Sunny" Balwani
CR-18-00258-EJD
Notice re Government's Intent to Introduce Certain Evidence

Dear Counsel:

We write to provide notice that the government may seek to introduce certain evidence in its case in chief in the above-referenced matter. This evidence is relevant to the charges in this case and is admissible to show, among other things, Defendants' motive, opportunity, intent, preparation, plan, knowledge, identity, consciousness of guilt, or absence of mistake or accident. See Fed. R. Evid. 404(b).

Please note that, by providing this disclosure, the government is not conceding that this evidence is admissible only under the provisions of Rule 404(b). The government may also assert that this evidence is admissible as direct evidence of the charged conduct, that it is inextricably intertwined with the events charged in the operative Indictment, or that it shows a continuing course of conduct otherwise admissible under Rules 401 and 402.

The facts summarized below are supported by the evidence in the government's discovery production, including witness statements as reflected in summary memoranda and source documents such as emails, laboratory reports, and business records.

This notice supplements the previous 404(b) disclosures that have accompanied the government's discovery productions in this case. The government reserves the right to introduce additional evidence covered by those previous disclosures, and further reserves the right to amend this notice in advance of trial based on its continuing investigation and trial preparation.

1. **False and misleading representations directed at insured patients.** As part of Defendants' scheme to defraud patients, they falsely represented to patients that Theranos's tests were accurate, reliable, and suitable for use in the clinical context, when Defendants knew that Theranos's tests were not properly validated and suffered from accuracy problems that rendered them unreliable and not suitable for informing clinical treatment decisions. Defendants caused Theranos to misrepresent the accuracy and reliability of its tests in advertisements and other promotional materials distributed electronically and in print, and further misled patients as to the nature of Theranos's tests by offering their tests for use in the clinical context, necessarily implying that Theranos's tests could be relied upon for medical decision-making. Patients who questioned or complained about Theranos's test results were falsely told that the company was having temporary, isolated problems with individual assays, were falsely assured that Theranos's tests could be relied upon, or were given other excuses that masked the limitations of Theranos's technology. Defendants also misled insured and uninsured patients regarding the methods of blood collection used by Theranos, causing patients to believe that they could have any blood test performed using a finger-stick when Theranos relied on vein draws for a substantial portion of its tests. These misrepresentations were directed at all potential customers of Theranos, including patients with and without medical insurance that might cover the cost of Theranos's tests. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, doctors and patients who patronized Theranos, marketing personnel employed or retained by Theranos, and former employees of Theranos.

2. **False and misleading representations directed at doctors.** As part of Defendants' scheme to defraud patients, they falsely represented to doctors that Theranos's tests were accurate, reliable, and suitable for use in the clinical context, when Defendants knew that Theranos's tests were not properly validated and suffered from accuracy problems that rendered them unreliable and not suitable for informing clinical treatment decisions. Defendants' misrepresentations came in multiple forms, including advertising and promotional materials distributed electronically and in print, directed at doctors and health professionals acting as patient representatives who would later advise patients as to which blood testing services they should use. Defendants also caused misrepresentations to be directed at doctors during real-time conversations between doctors and Theranos representatives. For example, Dr. Linnerson in the Phoenix area was falsely told by Theranos representatives that the company's tests had obtained FDA approval. Similarly, doctors who questioned or complained about Theranos's test results were falsely told that the company was having temporary, isolated problems with individual assays, were falsely assured that Theranos's tests could be relied upon, or were given other excuses that masked the limitations of Theranos's technology. Other doctors were deceived as to the equipment and methods used for Theranos's tests, with the company withholding information necessary for doctors to place those test results in context. See below. Defendants also misled doctors regarding the methods of blood collection used by Theranos, causing doctors to believe that patients could have any blood test performed using a finger-stick when Theranos relied on vein draws for a substantial portion of its tests. Similarly, Defendants misled some doctors regarding the equipment on which Theranos's tests would be run and the location of that equipment. Specifically, when Theranos partnered with doctors' offices to provide testing services in-house, Theranos would acquire office space within or near the doctor's practice and lead the doctor to believe that Theranos was maintaining and operating one of its small, Theranos-manufactured analyzers onsite. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but

not limited to, doctors and patients who patronized Theranos, marketing personnel employed or retained by Theranos, and former employees of Theranos.

3. **False and misleading representations made to Theranos's Board of Directors.** Defendants deceived Theranos's Board of Directors in furtherance of their schemes to defraud investors and patients. In particular, Defendants misrepresented the capabilities of Theranos's technology to the Board, making false claims about matters including: the capabilities of Theranos's analyzers; the accuracy and reliability of Theranos's tests; the existence of data proving the accuracy and reliability of Theranos's tests; the extent to which Theranos relied on third-party analyzers; the extent to which Theranos relied on vein draws; the nature of FDA's approval requirements for Theranos's tests; the extent to which Theranos's technology had been validated by other entities and organizations including hospitals; the success of Theranos's relationship with Walgreens; the revenues and financial health of the company; the truth of facts reported in the *Wall Street Journal*'s October 15, 2015 article discussing Theranos; and Defendants' willingness to submit Theranos's devices for independent testing or conduct comparison testing matching Theranos's test results against those from conventional labs. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, members of Theranos's Board of Directors.

4. **False and misleading representations made to Walgreens.** In pursuing and maintaining Theranos's partnership with Walgreens, Defendants made misrepresentations to Walgreens representatives about matters including: the number of tests Theranos's analyzer could perform using a sample drawn from a finger-stick; the number of assays Theranos's devices could conduct on a single sample; whether Theranos's technology was mature and ready for commercial launch; the existence of technological boundaries affecting Theranos's ability to scale up its testing services; the accuracy and reliability of Theranos's tests and whether those tests were as accurate as or more reliable than competing tests from conventional labs; the extent to which Theranos relied on third-party analyzers; the extent to which Theranos relied on vein draws; the nature of FDA's approval requirements for Theranos's tests; whether Theranos conducted adequate proficiency testing; the extent to which Theranos's technology had been validated by other entities and organizations including pharmaceutical companies and research universities who had purportedly used Theranos's testing services for clinical trials or other studies; the purported use of Theranos's technology by the United States military; Theranos's ability to provide decentralized testing services at the point of care and the company's experience operating under that model; and the profitability and financial health of the company. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to former Theranos employees as well as Walgreens personnel.

5. **False and misleading representations made to Safeway.** In pursuing a partnership between Theranos and Safeway, Defendants made misrepresentations to Safeway representatives about matters including: the number of tests Theranos's analyzer could perform; the number of assays Theranos's devices could conduct on a single sample; the accuracy and reliability of Theranos's tests; whether Theranos's technology was ready for commercial launch; the extent to which Theranos relied on third-party analyzers; the extent to which Theranos relied on vein draws; the nature of regulatory approval requirements for Theranos's tests; the extent to which Theranos's technology had been validated by other entities and organizations including pharmaceutical companies and research universities; the use of Theranos technology by the military; and the financial

health and projected profitability of the company. Additionally, Holmes agreed to provide a Theranos analyzer to UCSF so that they could evaluate Theranos's technology partly for Safeway's benefit. Theranos, however, never provided UCSF with a device to review. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees and Safeway representatives.

6. **False and misleading representations made to journalists.** In promoting Theranos's business, Defendants and their representatives were interviewed by journalists and made a number of false and misleading statements to those journalists regarding the state of Theranos's business and the capabilities of Theranos's technology. For example, Holmes made several misrepresentations to reporter Roger Parloff, including: (1) that Theranos's level of quality and low coefficient of variation was revolutionary for a certified lab; (2) that Theranos had done 70 or more tests from a single microsample; (3) that Theranos was different from labs that used large machines in a centralized process; (4) that Theranos was exceeding requirements for proficiency testing; (5) that Theranos's platform could do all of the several hundred tests offered by Quest in a regional lab; (6) that Theranos had a single device that could perform any test; and (7) that Theranos's clinical laboratory consisted of hundreds of Theranos analyzer devices. Simultaneously, Defendants did not correct the false conclusions that journalists reached based on Defendants statements, failing to clarify, for example, that Theranos's analyzer could perform only a limited number of assays and the company relied on third-party analyzers for a significant portion of its tests. Moreover, when Defendants saw false statements about Theranos's capabilities repeated in press coverage, they did not correct those reports. This remained the case even when other employees brought the inaccurate statements to their attention—for example, Theranos attorney Brad Arington confronted Holmes about multiple false statements in Roger Parloff's June 2014 *Fortune* article about Theranos. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees and attorneys as well as journalists who covered Theranos and conducted interviews of either Defendant.

7. **Fostering culture of secrecy and forcing employees and others to sign non-disclosure agreements.** In order to prevent the spread of information regarding problems at Theranos, Defendants required employees to sign strict non-disclosure agreements. Similar agreements were prerequisites to board members, potential investors, and other visitors obtaining information about the company, its technology, and its business. Similarly, in their roles controlling the day-to-day operations of Theranos and overseeing the company's employees, Defendants took steps to silo information within Theranos, discouraging employees from sharing information about their work with other employees in the company and fostering a culture of internal secrecy. These actions minimized the number of Theranos employees who were aware of problems relating to the company's research and development practices, technological capabilities, clinical laboratory practices, and business relationships. In particular, Defendants discouraged employees from sharing information regarding Theranos's use of third-party analyzers for its tests, taking specific steps to conceal this fact from employees who did not already know. Those steps included renaming third-party devices in Theranos's information management systems and assigning them code names so that employees who accessed these systems could not determine that those devices had in fact been manufactured by third-party companies. Defendants were so restrictive in controlling employees' statements about Theranos that they required some employees to remove references to Theranos from the employees' LinkedIn profiles. Defendants were similarly secretive

with investors, refusing to disclose to representatives like Lisa Peterson the identities of other investors in the company. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees and investors as well as potential and actual strategic partners of Theranos.

8. **Restricting access to laboratory areas within Theranos.** Defendants set policies at Theranos that severely restricted access to the laboratory areas where Theranos tested patient samples. Employees who did not work in the clinical laboratory generally were not able to access the areas, and visitors generally were not allowed to view those areas. These policies and practices prevented the dissemination of knowledge regarding problems with Theranos's proprietary analyzers as well as Theranos's use of third-party devices for many of its tests. Similarly, while withholding access to the actual clinical lab, Defendants misled visitors to Theranos by intentionally giving them the impression that the clinical lab consisted of multiple Theranos TSPUs and did not include other conventional devices. For example, when Vice President Biden visited Theranos in July 2015, Theranos did not show visitors the CLIA lab where patient sample testing was performed, but set up a room containing a large number of Theranos TSPU boxes on shelves, intending that visitors believe they were viewing the machines that ran Theranos's clinical tests. Within Theranos's Normandy laboratory, Balwani ordered that wall dividers be installed to hide the Tecan devices Theranos used to dilute its samples. When Holmes was interviewed by Roger Parloff following his visit to Theranos's facilities, she responded to his request to see the lab by indicating that he had essentially already seen the lab because he had seen a room with multiple TSPU devices. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees, potential and actual strategic partners of Theranos, journalists, and others who visited Theranos.

9. **Harassing, threatening, or otherwise influencing doctors or patients who had negative experiences with Theranos.** When doctors or patients made public statements about inaccurate Theranos test results and other negative experiences with the company, Defendants and their agents engaged in harassing, threatening, or other improper behavior in an effort to dissuade those providers from generating negative publicity for Theranos. For example, when Arizona provider Dr. Nicole Sundene was cited in a *Wall Street Journal* article after providing information about an unreliable Theranos test result, Balwani visited her offices in person along with Christian Holmes and berated her and her staff, threatening to sue her. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees as well as doctors and patients who patronized Theranos's testing services.

10. **Threatening, influencing, or vilifying journalists in response to negative coverage of Theranos.** When journalists investigated Theranos and wrote articles exposing misrepresentations made by Defendants concerning Theranos's business and technology, Defendants and their agents threatened and other attempted to improperly influence those journalists in an effort to suppress negative publicity. For example, when Defendants learned that a reporter from the *Wall Street Journal* was investigating the company and planning to publish an article reporting unfavorable facts about the company and its technology, Defendants directed attorneys to reach out to the *Wall Street Journal* and attempt to dissuade the publication from releasing the article. In a meeting with the reporter, John Carreyrou, his editor, and the publication's lawyers, Theranos's attorneys

insisted that the publication not move forward with the article, incorrectly claiming that it was based on false information. Holmes also attempted to persuade Rupert Murdoch exercise his power as owner of the *Journal* to kill the story before it could be published. Defendants also vilified journalists who printed negative articles about Theranos, blaming them for skepticism regarding Theranos and its technology in an effort to deflect blame and accountability from themselves and their company. For example, following publication of the October 15, 2015 *Wall Street Journal* article revealing problems with Theranos's blood testing services, Defendants on at least two occasions led employees in a chant of "Fuck you, Carreyrou," directed at the journalist who investigated and authored the article. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees, attorneys representing Theranos or relevant news publications, and journalists who investigated and covered Theranos.

11. **Blaming and vilifying competing companies.** When Theranos was the subject of regulatory scrutiny or negative publicity, Defendants attributed blame to competing companies like Quest and LabCorp, stating and implying that those companies were influencing the government and/or the media. For example, after October 2015, when Theranos became the target of unfavorable reporting exposing problems with the company's operations, Holmes led employees in a chant of "Fuck you, SonoraQuest." Defendants made statements during this time period arguing that Theranos had been unfairly targeted for criticism as a result of action by competitors given Theranos's potential to disrupt the blood testing industry. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees as well as journalists who covered Theranos.

12. **Threatening or intimidating employees and former employees.** Defendants and their agents directed threats and intimidating language at current and former Theranos employees in an effort to discourage employees from disseminating facts about the problems facing the company's technology and business. On multiple occasions, when employees left the company voluntarily or were terminated, Defendants corresponded or met with those employees to deliver stern reminders of the employee's obligations under nondisclosure agreements and threatened employees with consequences should they reveal any nonpublic information about Theranos's technology or business practices. When Dr. Adam Rosendorff resigned from Theranos, Balwani became angry Rosendorff had forwarded work emails to his personal account out of a fear that regulatory authorities might investigate Theranos's practices. Balwani insisted that Rosendorff sign a legal document confirming deletion of the emails. This exchanges caused Rosendorff to feel threatened. On other occasions, Defendants reacted angrily and attempted to threaten or intimidate employees whom they suspected to be the sources of negative publicity concerning Theranos. For example, following their review of some or all of the October 15, 2015 *Wall Street Journal* article discussing Theranos, Defendants directed board member George Schultz and Theranos attorneys to meet with Theranos employee Tyler Schultz because they believed some of the information in the article was provided by him. George Schultz conveyed to Tyler Schultz the warning from Defendants that Tyler's career would be adversely affected if he continued to share information about Theranos. During that conversation, Theranos lawyers waited at the house of Tyler Schultz's grandfather, subsequently ambushing Tyler Schultz and threatened him with legal action. On another occasion, Balwani became aware of a negative review of Theranos as an employer posted on website glassdoor.com. In response, Balwani aggressively interrogated several employees in an unsuccessful effort to determine the

source of the review and discourage further negative reviews. Generally, Holmes and Balwani fostered a culture that strongly discouraged skepticism or dissent from employees, enforcing that culture by reacting with hostility and intimidation to any questioning. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees and members of the Board.

13. **False and misleading representations made to FDA, CMS, CDPH, and other regulatory organizations.** When Theranos was the subject of inspections by CMS and other regulatory organizations, Defendants' agents presented regulators with selected, non-comprehensive data of Theranos's test results in an effort to mask accuracy and consistency problems with Theranos's assays. Additionally, Theranos failed to develop, maintain, and follow appropriate standard operating procedures for its clinical lab, but drafted and/or approved such SOPs immediately before or during regulatory inspections in an effort to conceal this oversight. In connection with an inspection by CDPH, Balwani and others misled an inspector into believing that the Theranos CLIA laboratory was limited to a single area. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees as well as regulatory agency personnel.

14. **Violations of industry standards and government regulations or rules regarding research and development procedures, medical devices and clinical laboratory practices.** In furtherance of their scheme to defraud, Defendants disregarded and failed to conform to industry standards as well as government regulations or rules regarding research and development procedures, medical devices and clinical laboratory standards. For example, in conducting research and development purportedly aimed at validating its assays, Theranos failed to conduct adequate validation studies, relying on insufficient data to claim that their tests were valid, accurate, and reliable. Theranos also cut corners in its Arizona research and development testing, failing to implement a clear protocol for informed consent for trial participants and fostering a coercive environment for testing. Theranos's CLIA lab was the site of several violations of these rules and standards including the use of expired reagents, failure to implement and carry out proper proficiency testing and quality control processes, and inadequate record-keeping. Under Defendants' supervision, Theranos's CLIA lab also improperly failed to develop, maintain, and follow adequate standard operating procedures for its clinical tests. Defendants also exercised an improper degree of control and influence over the operation of Theranos's CLIA lab despite their lack of medical education or training. Defendants, and Balwani in particular, were deeply involved in clinical decisions that should have been left to the discretion of the laboratory director—even overruling the laboratory director at times. In exercising that control, Defendants consistently made decisions that prioritized preserving Theranos's reputation and secrecy at the expense of providing complete information to doctors and patients. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees as well as regulatory agency personnel, and expert witnesses.

15. **Altering or tampering with third-party medical devices.** Theranos's in-house manufactured analyzer—called the Edison, miniLab, or TSPU—was incapable of performing a large proportion of the clinical blood tests Theranos offered. The Theranos devices were also incapable of handling high-throughput activity required to support Theranos's business model. In response, Defendants caused Theranos to acquire several commercially available blood analyzer devices manufactured by third parties. Theranos

then altered and tampered with those devices by modifying them to run on smaller and/or diluted blood samples, contrary to industry standards and the manufacturers' intended use for such devices. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees.

16. **Multiplexing test results and disregarding outliers to mask inconsistency.** In its clinical testing and/or its proficiency testing, Theranos operated its analyzers according to a protocol that included running each assay multiple times and then multiplexing the results in order to derive the final, reported result. As part of that protocol, so-called outlier results—individual results that deviated from the other results for a given assay on a given sample—were discarded and not accounted for. This approach tended to mask consistency problems with Theranos's tests. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees.

17. **Improperly setting and altering reference ranges.** Theranos's lab practices deviated from industry standards and standard testing protocols approved by FDA and validated by the industry. In setting the reference ranges for its tests, Theranos improperly relied on reference ranges for common, FDA-approved tests and/or conducted insufficient studies to set and adjust its own reference ranges. Similarly, after Theranos began offering and providing clinical blood testing services, the company improperly adjusted reference ranges based on individual clinical results—without conducting sufficient studies to justify such an adjustment—in order to bring out-of-range results back into the newly adjusted "normal" range and avoid abnormal results to patients. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees and expert witnesses.

18. **Withholding critical test results and other important information from doctors and patients.** In an effort to avoid additional scrutiny of its blood test results and laboratory practices, Theranos sometimes withheld test results that were in the "critical" range for a given analyte, i.e., results that indicated a patient might need urgent medical care. Additionally, Theranos withheld information from doctors and patients indicating what type of analyzer had been used for a given test, depriving doctors and patients of the facts needed to place certain assay results into context—for example, when multiple samples from a single patient had been run on different types of analyzers leading to otherwise unexplainable discrepancies in results. Theranos also withheld from doctors and patients the fact that Theranos's tests were not FDA approved, that Theranos relied on third-party analyzers for many of its tests, and other key facts regarding problems with their laboratory practices. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees, expert witnesses, and doctors and patients who patronized Theranos's testing services.

19. **Declining to conduct or agree to meaningful comparative tests.** Despite the fact that Theranos's analyzers and testing procedures varied from industry standards and conventional, FDA-approved tests, Defendants declined to conduct sufficient comparative tests establishing that Theranos's test results delivered accurate and reliable results when compared to competing technology. Similarly, Theranos failed to conduct comprehensive and accurate comparison tests establishing that its assays could reliably be conducted on finger-stick samples as opposed to vein draws. Defendants also refused

to commission or authorize such comparative testing through Sarah Cannon, Cleveland Clinic, UCSF, or other independent third-parties, to publish the results of any such testing, and to provide that information to the company's board. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees, expert witnesses, representatives of potential and actual strategic partners of Theranos, and members of the Theranos Board.

20. **Decommissioning Theranos's Laboratory Information System database.** Theranos maintained its clinical test data in a software database it called the Laboratory Information System ("LIS"). In October 2016, Theranos announced that it would cease offering clinical lab testing services. Following that decision but before the company ceased operation in 2018, Theranos "decommissioned" its LIS, rendering it nonfunctional and converting the data to a format that is not readily retrievable. This decision had the effect of obscuring or destroying detailed information regarding the specific tests Theranos conducted during the years of its clinical testing operation, hindering the government's investigation of Defendants. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees and representatives of the Theranos assignee.

21. **Obtaining personal benefit from position at Theranos.** In addition to their salaries and other direct compensation, Defendants also obtained significant additional benefits from their positions at Theranos. For example, the company regularly paid for luxury travel and accommodations for Holmes. Additionally, Holmes routinely required her office assistant to perform a large number of personal tasks seemingly unrelated to the business of Theranos, including shopping for and returning household items, clothing, luxury fashion accessories, and beauty products. Finally, both Holmes and Balwani were he beneficiaries of increased local and national standing as a result of their association with Theranos. Holmes was featured in numerous publications and lauded as a visionary. Defendants also associated with celebrities, dignitaries, and other wealthy and powerful individuals who were interested in Theranos. Holmes collected a substantial salary from Theranos, which enabled her to live a luxurious lifestyle, driving a luxury SUV, renting an expensive home, and purchasing expensive merchandise. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees, journalists who investigated Theranos, members of the Theranos Board, and potential and actual investors in Theranos.

22. **Concealing the romantic relationship between Holmes and Balwani from investors and others.** During much of the relevant time period, Defendants Holmes and Balwani were romantically involved. This relationship was actively concealed from others to whom its existence would have been material, including: prospective and actual investors; members of the Board of Directors; representatives of Walgreens, Safeway, and other partner organizations; Theranos employees; and journalists. Defendants took steps to hide the existence of this relationship, such as commuting to work separately and avoiding being seen together outside of work. On at least one occasion, when questioned by a journalist as to whether she was in a relationship, Holmes falsely stated that she was not. The government may introduce these and similar facts through produced documents as well as through testimony from witnesses including, but not limited to, former Theranos employees as well as members of the Board of Directors, potential and actual

investors in Theranos, potential and actual strategic partners of Theranos, and journalists who interviewed Defendants.

Very truly yours,

ADAM A. REEVES
Attorney for the United States,
Acting Under Authority Conferred
By 28 U.S.C. § 515

/s/
JOHN C. BOSTIC
Assistant United States Attorney